

REMARKS

A. Objection to the Specification Under 35 U.S.C. §132(a) and Rejection of Claims 39, 41-43, 45 and 47 Under 35 U.S.C. §112, First Paragraph

In the Office Action mailed on March 3, 2006, the specification was objected to under 35 U.S.C. §132(a) as introducing new matter into Claims 39, 41-43, 45 and 47. In particular, the limitation "determining that a blood component collection kit is compatible with the selected blood component collection application" was added to Claims 39, 43, 45 and 47 in the prior amendment, and the limitation "determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application" was added to Claims 41 and 44 in the prior amendment.

Applicants submit that neither of these limitations are new matter and that support for these limitations were in this patent application as originally filed. For example, the specification, at page 69, line 9 through page 70, line 9, explains that the phlebotomist scans the identification code of the blood collection kit to begin an apheresis procedure. All of the data associated with the

apheresis procedure are stored in a database. The system server then determines whether the blood collection kit is of the right type, whether the operator is authorized to perform the procedure and whether the apheresis instrument is approved.

Similarly, support can be found in the originally filed drawings of this application. For example, FIG. 69 lists blood component collection kits (PharmaCell-C Set) associated with a particular procedure (Bleed Number) and a particular operator (Howard). FIG. 87C is to the same effect. More specifically, FIG 106 in the first block on the third page states "The facility operator selects a blood collection kit, and scans the identification code associated with the blood collection kit. The identification code is compared to information on the systems server." Similarly, the second block on the third page of FIG. 106 states "The facility operator also scans his/her identity and transmits the information to the system server. The system server verifies that the operator is qualified to perform a planned procedure by checking against information on the system server." In either instance, an error message is issued if the scanned information does not match information already in the system server or database.

Applicants respectfully submit that adequate support exists for the prior claim amendments and that no new matter was added to the specification by such amendments. Reconsideration and removal of this objection are respectfully solicited.

The applicants submit that the rejection of Claims 39, 41, 43-45 and 47 under 35 U.S.C. §112, first paragraph, for an insufficient disclosure due to entry of the above prior amendments is also overcome for the same reasons as presented in the explanation above. Reconsideration and removal of this rejection are also respectfully solicited.

B. Rejection of Claims 1-47 Under 35 U.S.C. §102(e)

In the Office Action, Claims 1-47 were rejected under 35 U.S.C. §102(e) as anticipated by Fletcher-Haynes et al. U.S. Published Application No. US 2001/0034614 A1 (hereinafter "Fletcher-Haynes").

Independent Claims 39, 43, 45 and 47 have been further amended herein to include the step of scanning an identification code associated with the blood component collection kit and using the scanned identification code information to determine whether a blood component collection kit is compatible with a selected blood component collection application.

Fletcher-Haynes does not fairly teach or suggest the invention claimed in amended independent Claims 39, 43, 45 or 47 for the following reasons.

Fletcher-Haynes is generally concerned with manipulating and optimizing blood collection procedures to maximize the type or amount of blood components that may be collected from a particular donor. As an example, Paragraph 0195 of Fletcher-Haynes is concerned with an inventory of blood components (also referred to as "units"), i.e., platelets, plasma and RBCs, that have previously been collected. Thus, one of the objects of the optimization procedures of Fletcher-Haynes is to collect blood components that are not already in plentiful supply at the blood centers or hospitals. The selection of the blood component to be collected under the Fletcher-Haynes procedure is therefore not necessarily in accordance with any nomogram, as in the present invention, but is, instead, subject to external considerations of current inventories.

The manipulation and optimization techniques taught by Fletcher-Haynes are also directed to maximizing the blood component yield in a fixed time. See, e.g., the Abstract of Fletcher-Haynes.

Unlike the present invention, Fletcher-Haynes does

not fairly disclose or teach methods (Claims 39-44), systems (Claims 45-46) or media (Claim 47) that, inter alia, determines whether a blood component collection kit is compatible with a selected blood component collection application. While the Paragraphs 0015, 0062 and 0137 of Fletcher-Haynes have been cited in support of this rejection. Paragraph 0015 is general. Paragraph 0062 states that the tubing set may be selected prior to machine set up and prior to donor connection. Paragraph 0137 is concerned with changing the tubing set. None of these paragraphs is concerned with scanning an identification code associated with the blood component collection kit to confirm that the kit is compatible with a selected blood collection procedure, as presently amended herein.

The Applicants are not in agreement with the reasons cited in many of the rejections of the dependent claims. However, since independent Claims 39, 43 and 45 are believed to be patentable over the cited art, the dependent claims should also be allowable as placing additional limitations on independent Claims 39, 43 and 45.

Reconsideration and removal of the rejections of Claims 39-47 are respectfully solicited.

CONCLUSION

For the foregoing reasons, it is believed that Claims 39-47 patentably distinguish over the prior art and that these claims are in condition for allowance. Early allowance is respectfully solicited.

Attached to this Amendment is a petition for a one-month extension of time to make the filing of this Amendment timely.

It is believed that no additional fees are due. However, if any fees are applicable, kindly charge any such fees to our deposit account number 50-1039.

The Examiner is invited to call the undersigned to further discuss any of these matters.

Respectfully submitted,

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